IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS Susan Kamuda and Edward Kamuda, et al. Plaintiff/Petitioner 18 L 10475 Case No. v. Sterigenics U.S., LLC, et al. Defendant/Respondent SUBPOENA IN A CIVIL MATTER (For Testimony and/or Documents) To: U.S. EPA Region 5 77 W. Jackson Blvd. Chicago, Illinois 60604 YOU ARE COMMANDED to appear to give your testimony before the Honorable in Room Illinois on \bigcirc AM \bigcirc PM 2. \(\subseteq\) YOU ARE COMMANDED to appear and give your deposition testimony before a Notary Public at: in Room Illinois on \bigcirc AM \bigcirc PM YOU ARE COMMANDED to mail the following documents in your possession or control Kyle Pozan, Hart McLaughlin & Eldridge 22 W. Washington Street, Suite 1600, Chicago, IL 60602 06/04/2021 11:00 on or before • AM C PM (THIS IS FOR RECORDS ONLY. THERE WILL BE NO ORAL INTERROGATORIES.): See attached Request for Authorization Pursuant to 40 C.F.R. § 2.405.

Your failure to respond to this subpoena will subject you to punishment for contempt of this Court.

Description continued on attached page(s).

Dorothy Brown, Clerk of the Circuit Court of Cook County, Illinois cookcountyclerkofcourt.org

Notice to Deponent:	
1. 1. The deponent is a public or private corporation, privater(s) on which examination is requested are as	partnership, association, or governmental agency. The s follows:
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by	
(Name of Recording Device Operator) 3. No discovery deposition of any party or witnesses shat parties involved in the case, except by stipulation of the warrants a lengthier examination. Ill. Sup. Ct. Rule 200	ne parties or by order upon showing that good cause
• Atty. No.: 59648 Pro Se 99500	
Name: Kyle Pozan	
Atty. for (if applicable):	Issued by: /s/Kyle Pozan
Plaintiffs	Signature
Address: 22 W. Washington Street, Suite 1600	Attorney Clerk of Court
City: Chicago	Date:
State: IL Zip: 60602	
Telephone: (312) 971-9233	
Primary Email: kpozan@hmelegal.com	
I served this subpoena by mailing a copy, as required by	oy Ill. Sup. Ct. Rules 11, 12 and 204(a) (2), certified mail, return receipt requested
(Receipt #) on	I paid the witness \$ for
I served this subpoena by handing a copy to	
on I paid the witness \$	for witness and mileage fees.
/s/	
(Signature of Server)	(Print Name)

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, LAW DIVISION

Susan Kamuda and Edward Kamuda et al.,

Plaintiffs,

v.

Sterigenics U.S., LLC; Sotera Health, LLC; Bob Novak; Roger Clark; and GTCR, LLC;

Defendants.

No. 18 L 10475

Consolidated with:

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18 L 10183; 18 L 10477;
18 L 10479; 18 L 10510;
18 L 10695; 18 L 10744;
18 L 11004; 18 L 11005;
18 L 11006; 18 L 11252;
18 L 11275; 18 L 11743;
18 L 11939; 19 L 8807;
19 L 9163; 19 L 9167;
19 L 9169; 19 L 9170;
19 L 9171; 19 L 9173;
19 L 9174; 19 L 9175;
19 L 9176; 19 L 9177;
19 L 9178; 19 L 9179;
19 L 9180; 19 L 9181;
19 L 9182; 19 L 9186;
19 L 9188; 19 L 9189;
19 L 9190; 19 L 9196;
19 L 9197; 19 L 9198;
19 L 9200; 19 L 9201;
19 L 9202; 19 L 9205;
19 L 9206; 19 L 9207;
19 L 9213; 19 L 9214;
19 L 9215; 19 L 9216;
19 L 9362; 19 L 9454;
19 L 9508; 19 L 9528;
19 L 9732; 19 L 11410;
19 L 11510; 19 L 11682;
19 L 13010; 19 L 13486;
19 L 13488; 19 L 13493;
19 L 13517; 19 L 13518;
19 L 13522; 19 L 13537;
19 L 13538; 19 L 13539;
19 L 13540; 19 L 13541;
19 L 13544; 19 L 13545;
19 L 13546; 19 L 13550;
19 L 13551; 19 L 13552;
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19 L 13554; 19 L 13562; 19 L 13568; 19 L 13575; and 19 L 13576

Calendar R

Judge Christopher E. Lawler

PLAINTIFFS' REQUEST FOR AUTHORIZATION FOR REGION 5 OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY TO PRODUCE DOCUMENTS PURSUANT TO 40 C.F.R. § 2.405

Pursuant to 40 C.F.R. § 2.405, Illinois Supreme Court Rule 204(a), and 735 ILCS 5/2-1101, Plaintiffs request the authorization of the General Counsel of the United States Environmental Protection Agency ("EPA") to produce documents from Region 5 of the EPA in the above-captioned matter, currently pending in the Circuit Court of Cook County, Illinois. Plaintiffs seek the production of a limited set of documents on the topics listed below.

STATEMENT PURSUANT TO 40 C.F.R. § 2.405

- 1. As alleged in the enclosed Fourth Amended Master Complaint, attached as Exhibit A, Plaintiffs are individuals who lived and/or worked near Sterigenics U.S., LLC's ("Sterigenics") Willowbrook facilities and unknowingly breathed the excessive and dangerous amounts of ethylene oxide ("EtO") emitted by Sterigenics on a routine and continuous basis for years. As a result, they have been diagnosed with serious, and sometimes fatal, diseases or conditions.
- 2. Plaintiffs' complaint alleges that beginning in 1985, the EPA categorized EtO as "probably carcinogenic to humans." It further asserts that the EPA has cited and relied upon a long-term research study conducted by the National Institute for Occupational Safety and Health in the early 1990s on EtO's carcinogenic impacts on humans, which found causal links between exposure to EtO and increased mortality from lymphatic, hematopoietic, and breast cancers. The complaint also contends that in 2016, the EPA altered EtO's cancer weight of evidence descriptor from "probably carcinogenic to humans" to "carcinogenic to humans," and increased its estimate of EtO's cancer potency by 30 times. EPA concluded that EtO is carcinogenic to humans by the inhalation route of exposure with a stated confidence level of "HIGH." It also asserts that evidence recognized by the EPA indicates that inhalation exposure to EtO causes various cancers, including lymphatic cancers, leukemia, and breast cancer. Additionally, the complaint alleges that evidence recognized by the EPA indicates that inhalation exposure to EtO can cause an increased rate of miscarriages in females and a decreased sperm concentration and testicular degeneration in males.

Finally, the complaint points to the EPA's 2014 update to the National Air Toxics Assessment, which documented cancer risks in 76,727 census tracts across the country, showed that 106 census tracts had cancer risk scores above EPA's acceptable limits—the area surrounding the Willowbrook facilities was among those tracts. Notably, the complaint highlights that the EPA's assessment attributed 88.98% of the elevated cancer risk to EtO emissions.

- 3. Plaintiffs respectfully seek the production of a limited set of documents in the above-mentioned litigation.
- 4. Plaintiffs believe that the documents requested are in the public interest and will promote the EPA's mission to protect human health and the environment regarding the use of EtO. In fulfilling these primary functions, the EPA was extensively involved in matters pertinent to this litigation.
- 5. The requested documents are necessary for Plaintiffs to prove their allegations against Defendants and are unavailable by other means.
- 6. By limiting the document requests to narrow topics outlined below, Plaintiffs seek to avoid imposing an undue burden on the EPA or its employees.

DOCUMENT REQUESTS

- Documents and communications related to OIG Report and/or OIG Project No. OA&E-FY19-0091.
- 2. Documents and communications reflecting summaries or memos of interviews with staff and managers (see p. 4 of OIG Report).

- 3. Emails from OAR and Region 5 provided to OIG (see pp. 4-5 of OIG report).
- 4. Region 5's internal modeling of Sterigenics in November 2017 (see pp.8-9 of OIG report).
- 5. The December 2017 letter sent from Region 5 to Sterigenics requesting its review of modeling and suggestions for improvement and all related correspondence thereafter (see p. 8 of OIG report).
- 6. Documents and communications related to Region 5's monitoring on May 16-18, 2018 near the Sterigenics facility (see pp. 8-9 of OIG report).
- 7. Documents and communications related to the briefing provided to then-Region 5 regional administrator on or about June 20, 2018 about Region 5's May 2018 monitoring near the Sterigenics' facility (see p. 9 of OIG report).
- 8. The website and press release prepared by Region 5 to post the monitoring data on or about June 20, 2018 (see p. 9 of OIG report).
- 9. Documents and communications related to the direction received from the Office of Air and Radiation to not release the monitoring results or post the website disclosing the monitoring results (see p. 9 of OIG report).
- 10. The email from the then-Region 5 acting deputy regional administrator to staff working at the Region 5 Willowbrook site concerning the monitoring results dated on or about June 22, 2018, and all responses thereto (see p. 9 of the report).

- 11. The Letter Health Consultation sent by the ATSDR to a Region 5 manager on or about July 26, 2018, concerning the potential public hazard of the Sterigenics' facility (see p. 9 of OIG report).
- 12. The webpage posted on Region 5's website or about August 22, 2018 for about one hour concerning Sterigenics' facility monitoring (p. 9 of OIG report).
- 13. Documents and communications related to the direction received from the Office of Air and Radiation to take down the webpage posted on Region 5's website on or about August 22, 2018 (see p. 9 of OIG report).
- 14. Documents and communications related to instructions received by Region 5 from the Office of Air and Radiation to (i) not conduct inspection at EO facilities unless invited by the state; (ii) not issue CAA Section 114 letters to facilities, (iii) limit ambient air monitoring for EO to the Sterigenics facility; and (iv) not seek ATSDR's assistant for toxicological or health assessments and risk communications (see p. 14 of OIG report).
- 15. September 2018 stack test data from Sterigenics and any analysis, memos, or communications related thereto (see p. 17 of OIG report).
- 16. Documents and communications from "industry groups" concerning (i) the public release of information relating to the monitoring results near the Sterigenics' facility, including the timing of such disclosure; (ii) public disclosure of the health risks from ethylene-oxide emitting facilities in Illinois, including the timing of such disclosure (see Chapter 2 of the OIG report), or (iii) the government's

role in addressing of ethylene oxide emissions or achieving EPA's mission (see Chapter 3 of the OIG Report).

- 17. Communications with ATSDR (its agents or employees) regarding Sterigenics' Willowbrook facility.
- 18. Documents and communications related to any meetings, phone calls, video conferences, or other direct communications between industry groups (or any individual acting on their behalf) and any governmental employee in EPA, Region 5, ATSDR, OAR, or OAQPS, included but not limited to meeting minutes, computer notes, handwritten notes, attendance sheets, time sheets, or other documents generated or exchanged amongst individuals involved.
- 19. Documents and communications relating to the following statement at p. 18 of the OIG Report: "The monitoring results suggested that fugitive emissions were likely the source of high ambient concentrations given that the September 2018 stack test had shown that chamber back vent emissions had been controlled after being routed to existing control equipment. According to the EPA, the likely source of the majority of fugitive emissions at the Sterigenics facility was the off-gassing of sterilized products in uncontrolled areas of the facility."

DEFINITIONS

For the purposes of this request for authorization and accompanying letter, the following terms have the following meanings:

1. **Document**: The term "document" means a recording in any form whether written, electronic, audio, or video, and regardless of the medium on which

it is stored. The term also includes drafts, amendments, modifications, track-changes, and notations.

- 2. Communication: The term "communication" means any written, electronic, visual, or audio transmission, including but not limited to letters, memos, emails, texts, SMS messages, private messages or chats of any kind, regardless of the medium on which such communications are transmitted or stored.
- 3. OIG Report: The term "OIG Report" means the report entitled "EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions," dated April 15, 2021. The OIG Report is attached as Exhibit B.
- 4. Sterigenics: The term "Sterigenics" shall include Sterigenics U.S., LLC, Sterigenics International, LLC, Sotera Health, LLC, and their parent corporations, subsidiaries, affiliates, predecessors-in-interest, successors-in-interest, any and all persons acting on their behalf, including, but not limited to, employees, officers, managers, directors, associates, consultants, investigators, secretaries, assistants, agents, brokers, auditors, accountants, claims adjusters, or attorneys.
- 5. Industry Groups: The term "industry groups" means any business, organization, association, including any committees, lobbyists or representatives affiliated therewith, who operate or support the manufacturing of ethylene oxide or contract sterilization services using ethylene oxide. "Industry groups" include but are not limited to Sterigenics, Sotera Health, GTCR, Warburg-Pincus, American Chemistry Council, Inc., the Ethylene Oxide Sterilization Association, the Ethylene

Oxide Task Force, AdvaMed or the Advanced Medical Technology Association, and the Health Industry Manufacturers Association.

INSTRUCTIONS

- 1. These Requests cover all Documents and things, wherever located, in your possession, custody, or control, and in the possession, custody, or control of any of your attorneys, agents, employees, or other representatives.
- 2. If you cannot respond in full to any of these Requests, produce Documents to the fullest extent possible, specify the reason(s) for your inability to respond in full, including the location of non-produced Documents, and produce as many documents as you have concerning the unanswered portion(s).
- 3. To the extent that you believe any of the following Requests are objectionable, respond to as much of each Request as, in your view, is not objectionable and separately identify the portion of each Request to which you object and the grounds for your objection.
- 4. Documents should be produced as they are normally kept in the usual course of business, or should be segregated, labeled or otherwise marked as being responsive to a particular Request. Identical copies of responsive documents need not be produced. However, any non-identical copy of a Document that differs in any manner, including the presence of marginalia or other handwritten, printed, or stamped notations, shall be produced.
- 5. If you contend that any Document, that would otherwise have been produced, may be withheld or redacted on the ground that it is privileged under the

attorney-client privilege, the work-product doctrine, or any other basis, identify each such Document by providing a log which states

- a. The grounds upon which you believe the Document is privileged;
- b. Whether the Document has been withheld or redacted;
- c. The date of the Document or Communication;
- d. The author(s) of the Document or the Person(s) who participated m the communication;
- e. The recipient(s) of the Document or the Person(s) who received m the Communication;
- f. The title of the Document;
- g. The type of Document;
- h. The subject of the Document or Communication, except to the extent that you claim that the subject itself is privileged;
- i. The number of pages in the Document; and
- j. The specific Request, or Requests, to which the Document is responsive.
- 6. If in responding to these Requests you encounter any ambiguities when construing a request or definition, your response should set forth the matter deemed ambiguous and the construction used in responding.
- 7. If Documents are withheld based on an inability to locate or obtain the requested Document, state separately for each such Document the reason for the inability to locate or obtain the Document, and the steps taken to locate or obtain the document. If a responsive Document existed but has been destroyed, state the date

and circumstances of its destruction and identify all Persons having knowledge of these circumstances, including such Person(s)' name and known or last known home address, phone number, email address, and employer.

8. When interpreting these Requests, words in the singular also include their plural. Words in the plural also include their singular.

Exhibit A

FILED 4/16/2021 2:00 PM IRIS Y. MARTINEZ CIRCUIT CLERK COOK COUNTY, IL

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, LAW DIVISION

IN RE: WILLOWBROOK ETHYLENE OXIDE LITIGATION

This filing applies to: ALL ACTIONS
CONSOLIDATED FOR PRETRIAL AND
DISCOVERY PURPOSES

Consolidated for Pretrial and Discovery Purposes Under:

No. 2018-L-010475

2018L010475

Judge Christopher E. Lawler

PLAINTIFFS' FOURTH AMENDED MASTER COMPLAINT

Plaintiffs, by and through their attorneys, for their Complaint at Law¹ against Defendants STERIGENICS U.S., LLC, SOTERA HEALTH, LLC, BOB NOVAK, ROGER CLARK, GTCR, LLC, and GRIFFITH FOODS INTERNATIONAL, INC.,² allege as follows:

¹ Plaintiffs submit this Fourth Amended Master Complaint in accordance with prior Court orders, including CMO-1. In so doing, Plaintiffs maintain their position that this consolidated matter is not a mass action under 28 U.S.C. § 1332. In no way should this complaint be taken to mean that any Plaintiff is proposing any joint trials and/or joint decision of one or more issues in one or more cases. These matters have been consolidated for discovery and pretrial only based on certain Defendants' motion and the Court's own orders. Plaintiffs further submit this Fourth Amended Master Complaint in accordance with the Court's August 17, 2020 Order on Defendants' Motions to Dismiss, which dismissed certain counts of Plaintiffs' First Amended Complaint without prejudice. Plaintiffs hereby preserve Counts X (Sotera-Negligent Supervision), XII (Sotera-Strict Liability), XIII (Sotera-Battery), XXI (GTCR-Strict Liability), and XXII (GTCR-Battery) from their First Amended Master Complaint previously dismissed on August 17, 2020 for appeal, disclaim any waiver, and explicitly reserve the right to amend those counts as provided by the Court's dismissal without prejudice.

² Plaintiffs previously named Griffith Foods, Inc., Griffith Foods Worldwide, Inc., and Griffith Foods Group, Inc. as defendants in their Third Amended Master Complaint. The first two entities moved to dismiss that complaint pursuant to 735 ILCS 5/2-619 and produced a Declaration from William Frost stating, in relevant part, that these two entities never possessed any ownership interest in the Willowbrook facilities or in any entity owning any interest in the Willowbrook facilities, and that neither entity had any involvement with EtO sterilization services. *See* Frost Decl. at ¶¶ 17-18. Mr. Frost also attested that Griffith Foods Group, Inc. was merely the parent to Griffith Foods International, Inc., formerly known as Griffith Laboratories, U.S.A., Inc. *Id.* at ¶¶ 3-4. Plaintiffs have no reason to believe that Griffith's and Mr. Frost's representations to this effect are untrue and Plaintiffs are reasonably relying upon these representations

I. Prefatory Statement on Griffith Foods

- 1. In this Fourth Amended Complaint, Plaintiffs sue *only one Griffith entity*, referred to herein as "Griffith Labs." Today, Griffith Labs is known as "Griffith Foods International, Inc."; it was formerly known as "Griffith Laboratories U.S.A., Inc."
- 2. Plaintiffs sue Griffith Labs *only for its own independent acts and omissions* between 1984 and 1999, detailed extensively in this complaint. Plaintiffs do not sue Griffith Labs for the conduct of any other entity.
- 3. Sterigenics *has not assumed liability for the conduct of Griffith Labs.* (This is contrary to the Court's understanding at page 6 of its March 16, 2021 dismissal order). Indeed, in Stipulation No. 1, entered on June 12, 2020, Sterigenics assumed the liabilities of certain entities explicitly identified in the Stipulation, *but Griffith Labs is not one of them.*³
- 4. In this complaint, Plaintiffs specifically allege that Griffith Labs' misconduct persisted throughout the entirety of the period from 1984 to May 14, 1999, when Griffith Labs sold its sterilization business. *See* Paragraphs 33 104. Plaintiffs further describe how Griffith Labs' misconduct satisfies the elements of Plaintiffs various causes of action. *See* Paragraphs 275 324.
- 5. In summary, as alleged in this complaint, Griffith Labs' independent acts and omissions throughout the entirety of the period between 1984 and 1999, which caused or contributed to Plaintiffs' injuries, include:

in electing not to name Griffith Foods, Inc. Griffith Foods Worldwide, Inc. and Griffith Foods Group, Inc. in their Fourth Amended Master Complaint.

³ Stipulation No. 1 only applies to the approximate 70 plaintiffs who had filed suit at the time the stipulation was entered on June 12, 2020; it does not apply to the hundreds of plaintiffs who filed suit after, all of whom expressly disclaimed that stipulation in their respective complaints.

- a. Locating, and then for the next 16 years operating, controlling and/or maintaining, an EtO sterilization facility in the residential community of Willowbrook despite knowing at all times that EtO is very dangerous to human health and that area residents, workers, and schoolchildren would be unknowingly breathing daily the facility's EtO emissions, significantly increasing their risk of contracting cancer and other serious illnesses.
- b. Never warning its neighbors that they were in danger because of the Willowbrook facility's EtO emissions, even though Griffith Labs knew that the emissions threatened their health and that they had no ability to protect themselves because they had no idea that EtO was even being emitted into their community. Griffith Labs failed to warn the Willowbrook community even though it provided warnings to residents living near other Griffith Labs' EtO sterilization facilities in other states.
- c. Deciding and mandating that the Willowbrook facility operate without essentially any emission control equipment whatsoever for its first four years of operation (1984 1988), even though Griffith Labs knew that this violated the standard of care and would result in its neighbors being unnecessarily exposed to more than 500,000 pounds of EtO emissions during that time.
- d. Deciding to operate the Willowbrook facility for the entirety of the 1984 1999 time period without any control over EtO emissions from, e.g., the facility's back-vents, aeration rooms, and work aisles, even though Griffith Labs knew that this too violated the standard of care and would result in its neighbors being unnecessarily exposed to at least 400,000 pounds of EtO emissions (in addition to those emissions alleged in subparagraph (c), above) during that time.
- e. Designing in 1984, and then from 1984 to 1999 mandating the use of, a sterilization/emissions process that Griffith Labs knew violated the standard of care and was inadequate to protect the health of its neighbors against EtO emissions from the facility.
- f. Throughout the period from 1984 to 1999, itself directly purchasing, using, and mandating the use of sterilization and emission control equipment that Griffith Labs knew violated the standard of care and was inadequate to protect the health of its neighbors against EtO emissions from the facility.

- g. Failing to use emission control equipment in Willowbrook that it (Griffith Labs) was using in its other EtO facilities in the United States and other countries. This resulted in EtO emissions from the Willowbrook facilities that were sometimes as much as 100x higher, and more dangerous, than those at Griffith Labs' other facilities.
- h. Failing to test the air outside the Willowbrook facility (ambient air) to determine the concentrations of EtO that had been emitted from the facility and would be inhaled by Griffith Labs' neighbors, even though Griffith Labs knew those concentrations would be health threatening, and IEPA had specifically and directly required Griffith Labs to conduct extensive ambient air testing in 1984 to 1986 as a special condition for granting Griffith Labs' permit to operate the Willowbrook facility.
- i. Misleading the State's regulator, IEPA, by, inter alia, failing to inform IEPA as to what it (Griffith Labs) knew about the dangers of EtO to human health; planning to emit more EtO from the Willowbrook facility than it had represented to induce IEPA to grant it (Griffith Labs) the initial Willowbrook permit; failing to advise IEPA that it was not using the same caliber equipment and processes in Willowbrook that it was using at its other facilities; and reporting to IEPA EtO emissions that were based on assumptions Griffith Labs knew had no basis or were false.
- j. Failing to train its employees and failing to audit the Willowbrook facility to ensure that the facility's operations were not endangering its neighbors even though such training and auditing were Griffith Labs' responsibilities.
- k. Working independently and through an EtO industry lobbyist to improperly dispute conclusions concerning the health dangers of EtO that had been reached by independent scientists and health agencies in order to understate those health dangers and create a justification for emissions it knew endangered the health of those living near the Willowbrook (and other) sterilization facilities.
- 6. The above misconduct of Griffith Labs persisted well past its October 1984 nominal transfer to Micro Biotrol Company of certain (though far from all) assets and liabilities and at least until May 14, 1999. Indeed, as alleged above and throughout this complaint, this

October 1984 transaction did nothing to diminish Griffith Labs' substantive participation in the Willowbrook facility's operations and emissions.

7. In summary, Plaintiffs sue Griffith Labs because its actions and failures to act caused them to suffer the cancers and other serious illnesses that Griffith Labs specifically foresaw, when, in 1984, it purposely directed that an EtO sterilization facility be located in Plaintiffs' residential community that it (Griffith Labs) knew would endanger the community's health and safety, and then, for the next 15 years, directed that the facility be operated without the means necessary-indeed, for many years without any means at all-to protect the unsuspecting Plaintiffs against the facility's nearly one million pounds of carcinogenic emissions during that time. Griffith Labs may be held liable for this conduct, despite the fact that its subsidiaries were nominally operating the Willowbrook facility for portions of that 15 year period because, as the Illinois Supreme Court has determined, "[i]f a parent company specifically directs an activity, where injury is foreseeable, that parent could be held liable. Similarly, if a parent company mandates an overall course of action and then authorizes the manner in which specific activities contributing to that course of action are undertaken, it can be liable for foreseeable injuries." Forsythe v. Clark USA, Inc., 224 Ill. 2d 274, 290 (2007).

II. Introduction

8. For decades, tens of thousands of people have lived in the quiet but densely populated suburbs of Cook and DuPage Counties—Willowbrook, Burr Ridge, Darien, and Hinsdale—believing that their neighborhoods were safe and their air free from dangerous toxins. Not so. Defendants' Willowbrook sterilization facilities were emitting massive and unnecessary amounts of ethylene oxide ("EtO")—an invisible, odorless carcinogen—into their air.

- 9. There is no safe level of EtO; its carcinogenic effects have been widely known since the 1940s and known to Defendants since at least 1984. Notwithstanding, Defendants chose to operate their business and emit EtO in a densely populated area full of children, houses, parks, schools, and businesses.
- 10. Even further, although technologies to control EtO have been available—and widely used—since the 1980s, Defendants operated for years in Willowbrook without using the best practices and control technologies available to reduce their emissions; and as a direct and proximate result, the Willowbrook area has become one of the most toxic in the U.S. The people who have lived and worked in the area have inhaled EtO on a routine and continuous basis for years, unknowingly. Defendants never warned them about the danger it posed.
- 11. In August 2018, the U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry ("ATSDR") released to the public a report titled "Evaluation of Potential Health Impacts for Ethylene Oxide Emissions." That report, documenting the public health impacts of Defendants' emissions on the Willowbrook area, revealed the area's staggering and disproportionate risks of cancer.
- 12. In February 2019, the Illinois Environmental Protection Agency ("IEPA") ordered Defendants' Willowbrook facilities to stop using EtO. In the months that followed, Sterigenics U.S. announced a plan to install equipment to reduce emissions of EtO to 85 lbs. per year a drastic reduction from the thousands of pounds of EtO emitted in the years prior. Before

⁴ https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics International Inc-508.pdf

implementing the plan, however, Sterigenics U.S. announced the permanent closure of its Willowbrook facilities effective September 30, 2019.

- 13. Plaintiffs lived and/or worked near Defendants' Willowbrook facilities. They unknowingly breathed the excessive and dangerous amounts of EtO emitted from the facilities on a routine and continuous basis for years. As a result, they have been diagnosed with serious sometimes fatal diseases or conditions, and/or have sustained severe personal injuries causing them to incur and endure medical bills, lost wages, pain and suffering, mental anguish, disability, disfigurement, reduced life expectancy, and loss of normal life.
- 14. Plaintiffs bring these personal injury claims against Sterigenics U.S., LLC ("Sterigenics U.S."), Sotera Health, LLC ("Sotera"), Griffith Labs, two managers, and a private equity firm GTCR, LLC ("GTCR).
- 15. In addition, since 2016, Sterigenics U.S. and Sotera, and their corporate investors and parents (including GTCR), have pursued a plan to escape accountability to those who have been sickened or have lost their lives, and thereby to cynically render this Court proceeding a sham. That is, they have funneled nearly \$1.3 billion in cash out of the Sterigenics U.S. / Sotera companies in just the last 34 months for distribution to wealthy venture-capitalist investors, such that the funds could never be used to compensate the victims who have come to this Court to seek justice. And they have made certain that even those assets not siphoned away would never be available to those victims, by pledging the assets to banks to guarantee repayment of billions in corporate borrowings, so that even if the companies failed, they would be used to pay the banks, not the plaintiffs who had proven their cases.

16. By these actions, Sterigenics U.S., Sotera, and GTCR *admit* culpability for the toxic exposure suffered by Plaintiffs, but intend never to be held accountable for it.

III. Parties and Venue

- 17. This is an Illinois controversy. This Complaint is brought by or on behalf of individuals who are or were citizens of Illinois, for injuries that occurred in Illinois, as a result of ethylene oxide emissions in Illinois, that were caused by Illinois Defendants' negligence and other wrongful conduct, all of which took place in the State of Illinois. This court is a proper venue under 735 ILCS 5/2-101.
 - 18. Greater than two-thirds of Plaintiffs to this Complaint are Illinois citizens.
- 19. All Plaintiffs to this Complaint were exposed to and inhaled EtO from Defendants' Willowbrook facilities on a routine and continuous basis.
- 20. Plaintiffs did not have notice that the injuries and damages at issue were wrongfully caused or that they were caused by Defendants' emissions of EtO until, at the earliest, August 21, 2018, when the ATSDR report was issued.
- 21. Defendant Sterigenics U.S., LLC, is a wholly-owned subsidiary of Sotera Health, LLC, and is a limited liability company organized under the laws of Delaware with its headquarters and principal place of business at 2015 Spring Road, Suite 650, Oak Brook, Illinois 60523.
- 22. Defendant Sterigenics U.S., under its current name and previously under other names, operated EtO sterilization facilities at 7775 Quincy Street in Willowbrook, Illinois (the "Willowbrook facility") and 830 Midway Drive in Willowbrook, Illinois, continuously and at all

relevant times. (The two facilities are referred to collectively herein as "the Willowbrook facilities" or "the facilities.")

- 23. Sterigenics U.S.'s predecessors who operated the Willowbrook facilities include: Micro-Biotrol Company, Micro-Biotrol, Inc., Griffith Micro Science, Inc., IBA S&I, Inc., and Sterigenics EO, Inc. Through a series of acquisitions, mergers, and name changes, Sterigenics U.S. has assumed the liabilities of these predecessor entities for their respective involvement in the operation of the Willowbrook facilities. (Sterigenics U.S. and its predecessors are referred to collectively herein as "Sterigenics U.S.".)
- 24. Defendant Griffith Foods International, Inc., was previously known as Griffith Laboratories U.S.A, Inc. ("Griffith Labs"). During certain times prior to May 14, 1999, which are detailed below, Griffith Labs operated the Willowbrook facilities. At all times prior to May 14, 1999, Griffith Labs directed and controlled the sterilization operations at the Willowbrook facilities. Further, at all times prior to May 14, 1999, Griffith Labs directly participated in the operation of the Willowbrook facilities. Defendant Griffith Foods International, Inc. is responsible for all acts and omissions of Griffith Labs as alleged herein. At all relevant times, Griffith Labs, now Griffith Foods International, Inc., had its headquarters and principal place of business in Alsip, Illinois, which is in Cook County. To be clear, Plaintiffs allege that Griffith Labs committed independent injurious acts and omissions separate and apart from, though alongside of, Sterigenics' acts and omissions.
- 25. Defendant Sotera Health, LLC, under its current name and previously under other names (first as Sterigenics International, Inc. and then as Sterigenics International, LLC), and as the sole owner, member, and "manager" of Sterigenics U.S., operated, managed, and/or

maintained and otherwise participated directly in Sterigenics U.S.'s operation of the Willowbrook facilities. (Defendant Sotera Health, LLC and its predecessors are referred to collectively herein as "Sotera.")

- 26. For example, Sotera took responsibility for, and participated directly in, the following functions in connection with the facilities' operations:
 - a. Preparing and implementing risk management plans regarding health, safety, and other risks posed by the facilities' use and storage of EtO to human health and the environment;
 - b. Conducting hazard reviews at the facilities;
 - c. Developing written operating procedures for training and guiding the work of operators;
 - d. Training operations employees;
 - e. Evaluating whether the facilities' systems and equipment were in proper working condition;
 - Implementing a program to monitor the physical condition of process equipment;
 - g. Investigating incidents;
 - h. Conducting safety audits;
 - Determining potential impacts on the surrounding community from worst-case and alternative-case releases of EtO;
 - j. Evaluating the facilities' accident history;
 - k. Developing procedures for notifying local, state and federal emergency planning and response agencies about chemical spills;
 - l. Developing an incident prevention program that includes the following:
 - i. Process Safety Information;
 - ii. Process Hazard Analysis;

- iii. Employee Training;
- iv. Mechanical Integrity;
- v. Pre-Startup Review;
- vi. Compliance Audits;
- vii. Employee Participation; and
- viii. Hot Work Permit.

m. Developing plans to address accidental release that includes the following:

- i. Computer controls;
- ii. Door interlock system;
- iii. EtO leak detection monitors;
- iv. Emission Control Systems to destroy residual EtO;
- v. Pressure Relief Valves;
- vi. Process Safety Information for employees;
- vii. Written SOPs for training and instructions to employees; and
- viii. New hire and annual refresher training.
- n. Applying for IEPA construction permits to allow structural modifications at the facilities, including modifications impacting the volume of EtO emitted;
- o. Holding the facilities' construction permit, as permittee, authorizing it to:
 - Modify EtO emissions controls including sterilization chamber exhaust vents;
 - ii. Operate the sterilization chamber exhaust vents without any EtO emissions controls; and
 - iii. Modify the operation of its sterilization equipment, such as aeration rooms, by allowing EtO emissions controls to be bypassed.

p. Holding the facilities' construction permit, as permittee, requiring it to:

- i. Operate EtO emission controls in a manner that complies with local, state and federal law;
- ii. Conduct operational monitoring for the EtO emissions controls to ensure compliance with plans previously submitted to EPA;
- iii. Enhance operational monitoring to address the effects of modification of EtO emissions controls;
- iv. Keeping records for operational monitoring for the EtO emissions controls affecting certain aeration rooms; and
- v. Notifying IEPA promptly of permit deviations including identifying the date, time, duration, description of the deviation, its

probable cause, corrective actions, if taken, and preventative measures, if taken.

- q. Certifying the facilities' permit compliance (or non-compliance) to the IEPA;
- r. Communicating with IEPA regarding permit violations and uncontrolled emissions events;
- communicating with IEPA about its emission control equipment, including its plans to exhaust EtO from its chamber back vents to the atmosphere;
- Monitoring and reviewing of the facilities' emission data to analyze the duration and quantity of EtO emissions released, including any excess emissions;
- u. Reporting to IEPA on the volume of the facilities' EtO emissions;
- v. Monitoring the facilities' emissions control equipment;
- w. Assessing the capacity of the EtO sterilization chambers at the Willowbrook facilities as compared to customer demand for its sterilization services;
- x. Deciding to add EtO sterilization chambers at the facilities to meet customers' demand;
- y. Inventorying hazardous chemicals stored at the facilities, including EtO; and
- z. Communicating with state and local emergency response groups about such hazardous chemicals, including EtO.
- 27. Sotera undertook these responsibilities and functions even though, as alleged elsewhere in this complaint, it failed to ensure implementation adequate to keep the community safe.
- 28. With respect to the Willowbrook facilities, the activities of Sterigenics U.S. and Sotera have been intertwined. Sterigenics U.S. and Sotera have routinely and publicly held

themselves out as a single entity – "Sterigenics" – engaged in operating EtO sterilization facilities throughout the country, including the Willowbrook facilities; and others, including Moody's Investor Services, for example, has always treated the Sterigenics entities as a single entity and issued them a single "Corporate Family Rating." Indeed, Sterigenics U.S. and Sotera have shared the same Chairman and CEO, the same Vice President, the same General Counsel & Secretary, the same President and COO, and the same Vice President for Environmental, Health & Safety. And they have shared a complete unity of interest, with Sterigenics U.S. acting as an instrumentality of Sotera to accomplish Sotera's business mission.

- 29. Defendant Bob Novak was the Operations Manager at the Willowbrook facilities since August 2003. He was responsible throughout this period for coordinating and overseeing the operation of the facilities, directing personnel at the facilities, implementing procedures, and ensuring overall safety at the facilities. Upon information and belief, Mr. Novak resides in Illinois.
- 30. Defendant Roger Clark was the Maintenance Supervisor at the Willowbrook facilities from the late 1980s until approximately 2015. Mr. Clark was responsible throughout this period for calibrating the internal EtO monitors and overseeing the maintenance activities at the facilities which included, among other responsibilities, monitoring and replacing emissions systems equipment. Mr. Clark resides in Cook County, Illinois.
- 31. In 2011, a private equity trust managed by GTCR acquired Sterigenics International, LLC (now Sotera), along with its subsidiaries (including Sterigenics U.S.) and parent companies, for \$675 million.⁵ From 2011 through the present, GTCR, with its principal

⁵ https://www.gtcr.com/gtcr-announces-agreement-to-acquire-sterigenics-international-inc/

place of business at 300 N. LaSalle Street, Suite 5600, Chicago, Illinois, has owned, operated, managed, and/or maintained Sterigenics U.S. and Sotera.

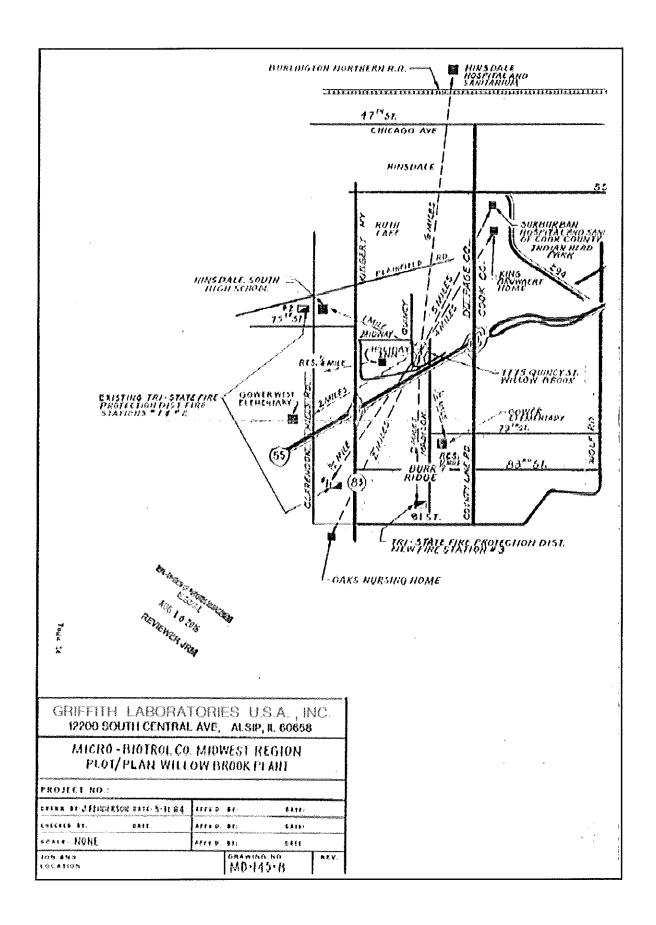
- 32. Defendants Sterigenics U.S., Griffith Labs, Sotera, and GTCR do regular and substantial business in Cook County, Illinois.
 - IV. Griffith Labs is responsible for EtO emissions from the Willowbrook facility up until at least May 14, 1999, when it sold its sterilization business
 - A. Griffith Labs decided to locate an EtO Sterilization facility in Willowbrook notwithstanding its knowledge that exposure to EtO is harmful to human health and can cause cancer
- 33. Griffith Labs claims to have pioneered the development and use of EtO as a sterilant in the 1930s. In the 1940s, Griffith Labs received patents for the EtO sterilization of hospital and medical supplies. Beginning in the 1950s, Griffith Labs began offering contract EtO sterilization to third-party customers. Griffith Labs continued its contract sterilization business for decades, and in or around 1984, it opened and operated an EtO sterilization facility in the Village of Willowbrook a suburban community located roughly 20 miles southwest of Chicago with a population of approximately 8,500.
- 34. Before 1984, Griffith Labs knew or should have known that it was too dangerous to locate an EtO sterilization facility in or near a residential community, and indeed that any sterilization facility anywhere should be equipped with emission control equipment adequate to ensure that no one outside the facility was exposed to EtO.
- 35. Griffith Labs' decision to locate its EtO sterilization facility in Willowbrook was driven by logistical and financial self-interest, such as Griffith Labs' belief that Willowbrook would be an optimal location because it is centrally located in the Midwest near highways and

railroads and because it was able to secure favorable lease terms. Griffith Labs' decision was also driven by a desire to expand its ethylene oxide sterilization services to the commercial sterilization of medical supplies. In making its decision, Griffith Labs ignored its knowledge that placing an EtO sterilization facility in or near a residential community would cause significant risk to human health. Griffith Labs could have secured a facility far enough away from a residential population to drastically reduce and/or minimize the danger to residents, but consciously chose not to.

- 36. On or about April 12, 1984, Griffith Labs, through its unincorporated division, Micro-Biotrol, Co6., leased a 44,939 square foot facility at 7775 Quincy Street in Willowbrook for the stated purpose of: "Sterilization process of various products." The lease terms were originally for five years, with multiple options to renew for another five years thereafter. In this way, Griffith Labs ensured that a dangerous EtO sterilization facility would operate next to a residential neighborhood in Willowbrook for many years to come.
 - B. Griffith Labs' dealings with IEPA in securing a permit to operate an EtO sterilization facility in Willowbrook
- 37. On or about May 31, 1984, in anticipation of constructing and operating the sterilization facility in Willowbrook, Griffith Labs created the plot below:

15

⁶ Sterigenics U.S. has also not assumed the liabilities for Micro-Biotrol, Co. Because Micro-Biotrol Co., was an unincorporated division of Griffith Labs, Griffith Labs is directly responsible for its conduct.



- 38. In making this plot, Griffith Labs marked off the distances from its EtO facility in Willowbrook to various schools, and therefore knew its facility would be located within ½ mile of Gower Elementary; one mile of Hinsdale South High School; two miles of Gower West Elementary; ¼ mile of the nearest residence to the west; ½ mile of the nearest residence to the south; and otherwise in the immediate proximity of many homes, parks, schools, and small businesses.
- 39. Griffith Labs further knew that EtO emissions from its Willowbrook facility could and would migrate to each of the locations on the plot, including those listed on the plot, in concentrations that would endanger human health.
- 40. Notwithstanding this knowledge, Griffith Labs elected to move forward with its plans to open an EtO sterilization facility in Willowbrook and, on or about June 1, 1984, applied for a construction and operating permit from IEPA.
- 41. Griffith Labs' permit application to IEPA included the above plot and also included a representation to IEPA that its maximum emissions of EtO would be 40 tons (80,000 lbs.) per year.
- 42. On or about July 6, 1984, Griffith Labs received the following letter from IEPA concerning the environmental impact of its proposed EtO emissions (highlighting added):



217/782-2113

I.D. No.: 043110AAC Application No.: 84060002

մայց 6, 1984

Griffith Laboratories 12200 South Central Avenue Alsip, Illinois 60658

Attention: John Kjellstrand

This is in response to a telephone call from Mr. Dickinson to Mr. Cobb on July 3, 1984, concerning the environmental impact of ethylene oxide emissions from the six proposed sterilizers included in the above mentioned construction permit application.

According to the information provided by your company in the application, the maximum emissions of ethylene oxide were 40 tons per year during 1983. The data you provided included a building which may cause a downwash effect, therefore, the ISCST model was used in the analysis. ISCST utilized one year of meteorology (1975 Midway), the urban dispersion mode and the building downwash option. Model results were obtained at 180 receptors located on five rings surrounding the source. Each ring contained 36 receptors spaced at 100 intervals. The rings were spaced at radial distances of 100, 400, 810, 1205, and 1609 meters from the source. According to the modeling run, the maximum annual ground level concentrations of ethylene oxide will vary from 3.120 micrograms per cubic meter at 100 meters to 0.09803 micrograms per cubic meter at one mile outside the plant boundary line. A copy of the modeled annual concentrations is attached.

The ethylene oxide (ETO) toxicity data was derived from different literature references. One such document is a USEPA draft publication --"Health Assessment Document - Ethylene Oxide - EPA 600-8-84-009A. copy of this document can be obtained by calling USEPA at phone number 513/684-7562.

The toxicity data provides evidence of human cancers of the pancreas, bladder, brain, central nervous system and stomach associated with E10 exposure. Various animal studies have shown carcinogenic, mutagenic, leukogenic and teratogenic effects. These studies indicate that the acceptable ground level concentrations of ETO is 0.007 micrograms per cubic meter. While the Agency does not have any established standards for ETO at this time, nor are we suggesting that the acceptable concentrations referenced above are necessarily the numbers that we are committed to using, in our opinion the emissions from the Micro Biotrol facility appear to be several magnitudes higher than desirable.



Page 2

We request a meeting as soon as possible to be able to better explain our evaluation and concerns. In our opinion, there are several methods by which emissions of ETO at this facility can be reduced. At our meeting, we wish to also discuss steps that can be taken to minimize emissions in order to reduce the ambient impacts to an acceptable level.

We are looking forward to hearing from you in the near future. In the meantime, should you have any questions, please feel free to call Jim Cobb, Harish Desai or me at 217/782-2113.

Very truly yours,

Bharat Mathur, P.E.

Manager, Permit Section

Division of Air Pollution Control

BM \QC:sd/1392d/24-25

cc: Narren Dickinson, Griffith Laboratories

Dennis Lawler Permit File Region 1

- 43. This July 6, 1984 letter from IEPA specifically addressed the "environmental impact" of ethylene oxide emissions from the sterilization chambers Griffith Labs sought to operate in Willowbrook. As Griffith Labs' Project Engineer for the Willowbrook facility later testified, the "environmental impact" from the facility included the neighboring residents' exposure to EtO and their resulting risk of contracting cancer.
- 44. By way of this July 6, 1984 letter, Griffith Labs was expressly advised by the state regulatory authority that its EtO sterilization operation posed significant adverse health risks to humans in that: (i) EtO exposure is associated with human cancers; and (ii) EtO has carcinogenic, mutagenic, leukogenic, and teratogenic effects. Griffith Labs thus had knowledge that its EtO

emissions would cause harm to humans in neighboring communities long before it exposed any Plaintiff's decedent to EtO emissions.

- 45. As Griffith Labs' Project Engineer later testified, IEPA was warning Griffith Labs by this letter that at least two of the schools and two residential areas on the plot (*see* Paragraph 37) were within the area where IEPA had determined that EtO concentrations from the Willowbrook facility would be "several magnitudes higher than desirable".
- 46. Indeed, Griffith Labs was already aware of the toxic and deadly effects of EtO when it received the July 6, 1984 letter from IEPA. Even before that date, and before any Plaintiff or Plaintiff's decedent was exposed to EtO emissions, Griffith Labs knew that:
 - a. there was "no safe level" of EtO, *i.e.*, there was no concentration of EtO that could be safely breathed without risk of serious damage to health;
 - b. "ethylene oxide has also been found to pose a serious health risk";
 - the very attribute which made EtO so lethally effective as a sterilant—
 e.g., its ability to inactivate DNA—also made EtO very dangerous for
 human beings exposed to it;
 - d. the state of Illinois recognized EtO as one of the 19 most dangerous chemicals (a "priority" pollutant);
 - e. EtO was suspected to cause cancer in humans, and threaten reproductive harm;
 - f. "the highly toxic nature of ethylene oxide and its classification as a suspect carcinogen";
 - g. any exposure to EtO that threatened to cause even one additional cancer in a population of 1,000,000 was unacceptable;
 - h. those exposed to EtO emitted from a sterilization facility were significantly more likely to contract cancer and other serious illnesses;

- i. EtO was a "mutagen", i.e., that it damaged human DNA in a way that promoted the development of cancer;
- j. "[t]here has been widespread recognition of the mutagenic potential of ethylene oxide";
- k. once emitted from a sterilization facility, EtO would be breathed by those living, working, and attending school near the facility; and
- "human receptors outside of the building may unknowingly come into contact with ethylene oxide before it has been sufficiently dispersed in the ambient atmosphere."
- 47. As a result, and well before it began operations in Willowbrook, Griffith Labs was acutely aware of the catastrophic risk to human health that inhalation exposure to EtO would create.
- 48. In addition to warning Griffith Labs about the health risks of EtO, the IEPA letter expressly told Griffith Labs that IEPA's air modeling raised substantial concerns that the surrounding Willowbrook community would be adversely impacted by Griffith Labs' EtO emissions. In particular, it informed Griffith Labs that: (i) emissions from the Willowbrook facility appear to be "several magnitudes higher than desirable"; and (ii) steps should be taken to "minimize emissions in order to reduce the ambient impacts to an acceptable level."
- 49. Moreover, Griffith Labs knew or should have known when it received IPEA's letter that IEPA's modeling results vastly understated the risk to Griffith Labs' neighbors that the Willowbrook emissions would pose. According to the letter, IEPA had based its EtO modeling in part on Griffith Labs' representation that its maximum emissions would be 40 tons (80,000 lbs.) per year. Upon information and belief, Griffith Labs knew that its emissions going forward would be significantly more than 80,000 pounds per year. In fact, in 1985, the Willowbrook facility

emitted more than 125,000 pounds of EtO. In each of 1986 and 1987, it emitted more than 160,000 pounds of EtO.

- 50. Further, Griffith Labs' representation to IEPA that it had emitted 40 tons of EtO during the year of 1983 was itself understated. In an internal memorandum dated May 3, 1984, Griffith Labs discloses that it had actually emitted approximately 50 tons in 1983. Griffith Labs never corrected its misrepresentation to IEPA.
- pollutant constitutes a major stationary emission source. Since our total emissions are approximately 50 tons per year (calendar 1983) and our anticipated growth is to 65 tons per year in 5 years, the part 203 does not
- 51. The same internal memo also predicted that Griffith Labs would grow to emit 65 tons per year. Griffith Labs did not disclose this fact to IEPA either.
- 52. As a result, Griffith Labs knew or should have known that IEPA's opinion that its emissions would be "several magnitudes higher than desirable" was based on modeling that only accounted for about half of what Griffith Labs actually intended to emit. Griffith Labs never corrected IEPA's modeling assumptions at any point prior to receiving its permit.
- 53. Separately, upon information and belief, Griffith Labs misinformed IEPA about the height of the stack it would use at Willowbrook to release EtO emissions. The height of the stack is important because, in general, the higher the stack, the greater the EtO concentrations will be diminished before they descend to the zone in which they are breathed by, e.g., residents, workers, and schoolchildren. In connection with its 1984 permit application, Griffith Labs told IEPA that the stack exhaust point would be 40-50 feet above grade. However, upon information and belief, the actual exhaust point was only 28 feet above grade.

- 54. As a result, Griffith Labs knew or should have known that IEPA's opinion that its emissions would be "several magnitudes higher than desirable" was based upon modeling that used a falsely inflated stack height. Griffith Labs never corrected IEPA's modeling assumptions at any point prior to receiving its permit.
- 55. Even further, Griffith Labs took essentially no action in connection with IEPA's stated concerns about its "minimiz[ing] emissions in order to reduce the ambient impacts to an acceptable level." Instead, once Griffith Labs received its permit, it operated without any emission controls designed to remove or eliminate EtO from emissions and thereby caused massive unfiltered emissions of EtO into the Willowbrook community 24 hours a day, 7 days a week, 365 days a year. Griffith Labs did so notwithstanding its knowledge that: (a) toxicity data showed that EtO exposure was associated with human cancers and other harms; (b) the facility was located within the immediate proximity of homes, parks, schools, and small businesses; and (c) IEPA's (understated) modeling predicted emissions "several magnitudes higher than desirable."
- 56. Indeed, by no later than 1982, Griffith Labs knew that emission control technology was available that could remove up to 99% of EtO from the Willowbrook facility's exhaust before it was allowed to enter Willowbrook's air. Despite knowing of the availability of this technology before operating in Willowbrook, Griffith Labs specifically declined to use it for essentially the first four years of Willowbrook operations.

- C. Griffith Labs' received an operating permit for the Willowbrook facility that was subject to special conditions with which Griffith Labs failed to comply
- 57. On July 30, 1984, IEPA issued Griffith Labs a Joint Construction and Operating Permit to construct and operate sterilization chambers 1, 3, 4, 5, 9, and 10 at the Willowbrook facility.



Illinois Environmental Protection Agency · 2200 Churchill Road, Springfield, IL 62706

217/782-2113

JOINT CONSTRUCTION AND OPERATING PERMIT

PERMITTEE

Griffith Laboratories, U.S.A., Inc. 12200 S. Central Avenue Alsip, Illinois 60658

Attention: Jo

John Kjellstrand

Application No.: 84060002

Applicant's Designation: STERILIZER

Subject: Gas Sterilization System

Date Issued: July 30, 1984

I.D. No.: 043110AAC

Date Received: June 1, 1984

Operating Permit Expiration

Date: July 31, 1986

Location: 7775 Quincy St., Willowbrook, Illinois

- 58. The permit was issued to "Griffith Laboratories, U.S.A., Inc." (i.e., Griffith Labs) for its operation of the Willowbrook facility. The permit had a two-year term, expiring on July 31, 1986. Griffith Labs never attempted to amend or correct this permit in any way, including to substitute any other entity as the permit holder.
- 59. The 1984 permit, as well as all permits relating to the Willowbrook facility issued thereafter, expressly warned Griffith Labs the permit did *not* release it from liability for harm to its neighbors. They stated:
 - a. the permit "does not release the permittee from any liability for any loss due to damage to person or property caused by, resulting from, or arising out

- of, the design, installation, maintenance, or operation of" the Willowbrook facility.
- b. the permit "in no manner implies or suggests that the [IEPA] . . . assumes any liability, directly or indirectly, for any loss due to damage, installation, maintenance or operation" of the Willowbrook facility.
- c. the Willowbrook facility could not be operated in such a manner as to "cause a violation of the Environmental Protection Act or Regulations promulgated thereunder," all of which forbid air pollution in the State of Illinois.
- 60. As the permittee for the Willowbrook facility, Griffith Labs was responsible for the following operations:
 - a. sterilization processes for the six chambers for which it received a permit;
 - b. emissions of EtO and other volatile organic materials from the facility;
 - c. the acquisition, installation, and operation of pollution controls at the facility;
 - d. testing and monitoring for levels of EtO both in the facility and the environment;
 - e. monitoring, testing, maintenance, and repair of all equipment involved in the sterilization processes at the facility;
 - f. maintaining emission records and reporting to IEPA and as otherwise required by law;
 - g. ensuring that its emissions and emission controls were compliant with local, state, and federal law;
 - h. monitoring and reviewing the facility's emission data to analyze the duration and quantity of EtO emissions released, including any excess emissions;
 - i. assessing the capacity of the EtO sterilization chambers at the Willowbrook facility as compared to customer demand for its sterilization services;

- j. inventorying hazardous chemicals stored at the facilities, including EtO; and
- k. communicating with state and local emergency response groups about such hazardous chemicals, including EtO.
- 61. Griffith Labs undertook these responsibilities and functions even though, as alleged elsewhere in this complaint, it failed in its duty to ensure that its implementation of these responsibilities and functions was adequate to keep the community safe.
- 62. In addition, as part of the 1984 operating permit issued to Griffith Labs by IEPA, several special conditions were imposed on Griffith Labs to address IEPA's concerns about the environmental impact of Griffith Labs' EtO emissions, including that:
 - a. Griffith Labs was required to conduct ambient air monitoring for a oneyear period and submit a final report by December 1, 1985; and
 - b. Griffith Labs was required to "investigate the availability of emission reduction measures for ethylene oxide."
- 63. Griffith Labs failed to comply with either special condition and, upon information and belief, misled IEPA as to both.
- 64. Griffith Labs' obligation to monitor EtO concentrations in the ambient air outside the Willowbrook facility required that monitoring be conducted at locations in between the facility and the local residents, workers, and schoolchildren. The plain intent of this requirement was so that Griffith Labs and IEPA would know the concentrations of EtO that were being emitted from the facility and carried by air currents into the surrounding neighborhoods. Ultimately, the monitoring would determine the extent of the threat to the health of Griffith Labs' neighbors posed by the facility's EtO emissions.

- 65. Despite its obligation to conduct such monitoring, and its knowledge that the purpose of the monitoring was to provide critical information about the seriousness of threats posed to its neighbors' health by its EtO emissions, Griffith Labs never monitored the ambient air nor ever made any effort to determine the ambient air EtO concentrations, such as by modeling them.
- 66. Instead, Griffith Labs told IEPA that the monitoring equipment it purchased was not dependable and was malfunctioning. But instead of trouble-shooting the equipment with the supplier or getting new equipment (which was readily available), Griffith Labs simply ignored the requirement that it conduct ambient air monitoring, thereby also ignoring the serious threat to human health posed to those who lived and worked near its Willowbrook facility.
- 67. Due to Griffith Labs' initial failure to comply with the ambient air monitoring requirement and submit a final report by December 1, 1985, IEPA "extended" Griffith Labs' deadline to do so until July 31, 1986. Griffith Labs, however, did not perform ambient air monitoring or submit a final report by that date, either. Throughout Griffith Labs' 15-year control of facility operations, it *never* performed the ambient air monitoring it had been told was necessary to perform back in 1984.
- 68. Upon information and belief, Griffith Labs made a decision not to conduct ambient air monitoring because (i) it did not care about the harm its EtO emissions would cause those who lived and worked in the Willowbrook community; and (ii) it knew that actual monitoring would reveal to regulators that its EtO emissions were too dangerously high to warrant continued operation of the facility—either at all, or without installing significant and expensive emission control equipment.

- 69. Griffith Labs' decision in this regard a classic example of "profits over people" exhibited reckless indifference and conscious disregard for the health and safety of its neighbors in the Willowbrook community.
- 70. Griffith Labs also failed to comply with and/or misled IEPA about the requirement that it "investigate the availability of emission reduction measures for ethylene oxide." Griffith Labs was told in March 1983 over one year before it submitted its permit application for the Willowbrook facility that a Deoxx emission reduction system was certified as "Best Available Control Technology" and that the system was available for about \$118,000. Even though Griffith Labs was well aware of the availability of this emission reduction technology for ethylene oxide when it applied for and received its permit, it stalled compliance with the requirement to purchase and implement it by falsely telling IEPA that it would have to "investigate [its] availability."
 - D. Griffith Labs' own independent acts and omissions contributed to cause Plaintiffs' injuries
- 71. Illinois law recognizes that multiple parties may contribute to cause a given injury. 735 ILCS 5/2-1117; *Sperl v. Henry*, 2018 IL 123132, ¶¶ 24-25 (2018).
- 72. At all times between 1984 and May 14, 1999, Griffith Labs was obligated to comply with the Illinois Environmental Protection Act and its supporting regulations, which prohibited "the emission of any contaminant into the environment so as to cause or tend to cause air pollution in Illinois;" defined as "emissions sufficient "to be injurious to human life [or] health."
- 73. Griffith Labs' conduct, as detailed in the paragraphs immediately below, breached its duty in this regard and was a substantial contributing factor in causing injury to every Plaintiff

or Plaintiff's decedent who lived and/or worked in the immediate vicinity of the Willowbrook facility up until May 14, 1999, when Griffith Labs sold the company.

Griffith Labs greatly enhanced the danger to its neighbors by expanding its EtO operations in Willowbrook

- 74. As discussed above, in 1984, Griffith Labs located an EtO sterilization facility in a residential community, knowing that area residents, workers, and schoolchildren would be exposed to the facility's EtO emissions, and as a result would be significantly more likely to contract cancer and other serious illnesses.
- 75. In 1999, Griffith Labs authorized and funded the establishment, construction, and operation of an additional EtO sterilization facility in Willowbrook (Willowbrook II), despite knowing that the first Willowbrook facility had never been operated safely, and that Willowbrook II could not be operated safely. The impact of Willowbrook II was to further inundate the Willowbrook area and its residents with thousands of pounds of unnecessary and dangerous EtO emissions, in addition to the EtO emitted from the first Willowbrook facility.
- 76. Griffith Labs also authorized and funded the use of several "off-site" facilities in the Willowbrook area, including facilities at: (i) 407 Heathrow Court in Burr Ridge; (ii) 417 Heathrow Court in Burr Ridge; (iii) 261 Shore Drive in Burr Ridge; (iv) 7409 Quincy Street in Burr Ridge; and (v) 16 W 151 Shore Court in Burr Ridge. Upon information and belief, these facilities were used to store or treat sterilized products that were still off-gassing EtO. Upon further information and belief, these facilities had no emission controls such that all residual EtO from the off-gassing products at those facilities was emitted directly into the atmosphere.

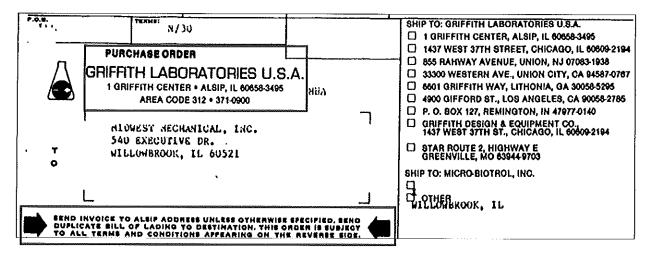
Griffith Labs failed to monitor and model ambient air concentrations

- 77. Griffith Labs never monitored or modelled to determine the concentrations of EtO from the Willowbrook facility that those in the Willowbrook area would be breathing, even though Griffith Labs was obligated to do so by its permit, as described in Paragraphs 62 67, above.
- 78. Griffith Labs knew that these monitoring results were very important to provide to IEPA so that it could do its job and determine whether the company was operating safely or unnecessarily dangerously.
- 79. In fact, it had conducted and/or authorized ambient air modeling and monitoring at other of its EtO facilities.
 - 80. Griffith Labs consciously chose *not* to do the same in Willowbrook.

Griffith Labs failed to timely or reasonably implement emission controls

- 81. At all times between July 1984 and May 14, 1999, Griffith Labs owned and controlled the sterilization and emission control equipment that was utilized at the Willowbrook facility. By participating in and authorizing the Willowbrook facility's decisions about the use of that equipment, Griffith Labs had the responsibility to ensure the adequacy of such equipment to protect its neighbors in the Willowbrook community. This is demonstrated, *inter alia*, by the following:
 - a. All expenditures for sterilization and emission control equipment used in the operation of the Willowbrook facility had to be authorized before purchase by Griffith Labs. Without such authorization, the equipment could not have been purchased or used at the Willowbrook facility. Simply, the facility could not have operated without Griffith Labs' specific authorization.

b. Griffith Labs purchased and authorized for use at the Willowbrook facility sterilization and emission control equipment without which the facility could not function. Griffith Labs accomplished this via "Griffith Laboratories U.S.A. Purchase Order[s]" which it directed to specific Griffith Labs' vendors. An example of the purchase orders used by Griffith Labs is depicted immediately below, with emphasis added to show that the entity ordering and paying for the equipment was Griffith Labs:



- c. Under its own "Griffith Laboratories U.S.A. Purchase Order[s]," Griffith Labs ordered equipment from its vendors, and directed the vendors to invoice Griffith Labs for payment thereon. Griffith Labs, in turn, paid the vendors for the equipment. For example:
 - In 1986, Griffith Labs direct its vendor, Phillips Electric, Inc., to supply and install one complete computer control system for the 12-pallet EtO sterilization chamber No. 2 at the Willowbrook facility.
 - ii. In 1986, Griffith Labs directed its vendor, Midwest Mechanical, Inc., to install one complete ventilation system for EtO sterilization chamber No. 2 at the Willowbrook facility.
 - iii. In 1986, Griffith Labs directed its vendor Midwest Mechanical, Inc., to install all mechanical equipment and pipe that equipment according to a specific drawing for EtO sterilization chamber No. 2 at the Willowbrook facility.
 - iv. In 1990, Griffith Labs direct its vendor, Midwest Mechanical, Inc., to install one complete nitrogen system for

- sterilization chamber No. 2 with piping and mechanical work at the Willowbrook facility.
- v. In 1991, Griffith Labs directed its vendor Midwest Mechanical, Inc., to supply labor and material and install purging systems for gassing stations 1, 2, 3, 5, 6, 7, 8, 9, and 10 at the Willowbrook facility.
- d. At all times between 1984 and 1999, Griffith Labs owned all sterilization and emission control equipment utilized at the Willowbrook facility.
- e. On multiple occasions during the 1980s and 1990s, and after October 1984, Griffith Labs-affiliated entities and/or Griffith Labs itself, while seeking permits to construct or operate the Willowbrook facility, represented to IEPA that Griffith Labs was the "Plant Owner." For example, a 1988 application for a permit to construct and operate the EtO sterilizer system in Willowbrook identifies Griffith Labs as the Willowbrook "Plant Owner."
- f. On multiple occasions during the 1980s and 1990s, and after October 1984, Griffith Labs-affiliated entities and/or Griffith Labs itself, while seeking permits to construct or operate the sterilization system at the Willowbrook facility, represented to IEPA that the "Owner" of the sterilization system was Griffith Labs. The same 1988 application to IEPA referenced above identifies Griffith Labs as the owner of the EtO sterilizer system which needed the IEPA permission for construction and operation.
- g. It was the Board of Directors of Griffith Labs which, on multiple occasions in the 1980s and 1990s, and after October 1984, supplied IEPA with the corporate resolution authorizing the operation of the Willowbrook sterilization system. Such authorization was legally required before IEPA could award a permit for the operation of a sterilization system at the Willowbrook facility. Indeed, the application specifically provides that:

THIS APPLICATION MUST BE SIGNED IN ACCORDANCE WITH PCB REGS., CHAPTER 2, PART 1, RULE 103(a)(4) OR 103(b)(5) WHICH STATES:
"ALL APPLICATIONS AND SUPPLEMENTS THERETO SHALL BE SIGNED BY THE OWNER AND OPERATOR OF THE EMISSION SOURCE OR AIR POLLUTION
CONTROL EQUIPMENT, OR THEIR AUTHORIZED AGENT, AND SHALL BE ACCOMPANIED BY EVIDENCE OF AUTHORITY TO SIGN THE APPLICATION."

IF THE OWNER OR OPERATOR IS A CORPORATION, SUCH CORPORATION MUST HAVE ON FILE WITH THE AGENCY A CERTIFIED COPY OF A RESOLUTION OF THE CORPORATION'S BOARD OF DIRECTORS AUTHORIZING THE PERSONS SIGNING THIS APPLICATION TO CAUSE OR ALLOW THE CONSTRUCTION OR OPERATION OF THE EQUIPMENT TO BE COVERED BY THE PERMIT.

Thus, pursuant to the legal requirements set forth in the permit application, any corporation that owned or operated "the emission source or air pollution control equipment," had to file a certified copy of a board resolution authorizing the construction or operation of the equipment. The *only* board of directors to supply such a resolution, or authorize the use of

the sterilization equipment at the Willowbrook facility, was Griffith Labs' (see below).

CERTIFIED COPY OF RESOLUTION Gregory L. Schmidt, Secretary of Griffith Laboratories, no Delaware Corporation, having custody of the corporate records thereof, do hereby certify that the Board of Directors adopted the following resolution during a Meeting of the Board of Directors, on May 23, 1984, which is in accordance with the law and the by-laws of said corporation. TITE THE RESOLVED, by the Board of Directors of the Company that it authorize Ralph A. Sair, its Senior Vice President or Donald E. Alguire or John Kjellstrand, respectively, President and Vice President of the Company's division, Micro-Biotrol Company, to cause or allow the construction or operation of the equipment to be covered by the Illinois Environmental Protection - Agency permit to construct and operate such equipment at the Micro-Biotrol facilities at 7775 Quincy Street, In witness whereof, I have hereunto subscribed my name as Secretary and have caused the corporate seal of said corporation Land State of May, 1984. The state of May, 1984. to be hereunto affixed, this 31st day of May, 1984. When the street in the street of t Secretary

Applications submitted to IEPA for Willowbrook facility permits in the 1980s and 1990s — and after October 1984 — included the above Griffith Lab's board resolution. No operator — not Micro-Biotrol or Griffith Micro Science — supplied such a board resolution.

- h. On multiple occasions during the 1980s and 1990s, and after October 1984, Griffith Labs-affiliated entities and/or Griffith Labs itself, while seeking permits to construct or operate the Willowbrook facility, represented to IEPA that the design of the facility's sterilization system was that of Griffith Labs'. Indeed, in the 1988 application to the IEPA for example, Griffith Labs' Process Flow Diagram, illustrating the EtO sterilization system process in order to obtain the permit, was submitted.
- i. Griffith Labs paid all permit and other regulatory fees relating to Willowbrook operations thereby, on each occasion, authorizing and

- funding the Willowbrook facility's continued operation and emission of dangerous amounts of EtO into the Willowbrook community.
- j. Griffith Labs mandated an operating strategy of seeking a competitive advantage by purchasing and directing the use of sterilization equipment designed to protect its workers and customers from exposure to EtO at the expense of exposing neighboring residents to even more EtO. Specifically, EtO concentrations inside the Willowbrook facility that were too dangerous for workers and customers to breathe were intentionally vented into the Willowbrook community, where they were breathed by area residents, workers, and schoolchildren.
- 82. When the Willowbrook facility first began operating, Griffith Labs decided not to use any emission controls whatsoever even though it knew such controls were available and necessary. Thus, despite its knowledge that EtO emissions from its Willowbrook facility would make it significantly more likely that area residents, workers, and schoolchildren would contract cancer and other serious illnesses, Griffith Labs designed the Willowbrook facility without the emission controls that Griffith Labs knew were necessary to prevent such catastrophic outcomes.
- 83. After about three years of operating without any controls, Griffith connected one of nine chambers to emission controls in July 1987. But, for the next nine months, until April 1988, Griffith Labs continued to operate eight of its sterilization chambers without any emission controls. As a result, for approximately the first four years of operation, close to 100% of all EtO used at the Willowbrook facility was emitted into the atmosphere.
- 84. Griffith Labs made this decision despite its knowledge that it would result in the unnecessary emission of hundreds of thousands of pounds of EtO during over these four years, and gravely endanger its neighbors' health.
- 85. Further, at all times between 1984 and May 14, 1999, Griffith Labs made a decision not to control EtO emissions from the Willowbrook facility's back-vents, aeration rooms, and

work aisles—three principal areas within the facility where EtO would collect after the products were sterilized.

- 86. As Griffith Labs knew or should have known, this failure to control emissions from, e.g., back-vents, aeration rooms, and work aisles resulted in the unnecessary emission of EtO into the surrounding community of at least 25,000 pounds each year, or a total of at least 400,000 pounds between 1984 and 1999.
- 87. Griffith Labs knew that these emissions, too, would gravely endanger its neighbors' health, but allowed them to occur anyway.
- 88. As a result of Griffith Labs' decisions, at no time between 1984 and 1999 was the emission control equipment at Griffith Labs' Willowbrook facility adequate to protect the health of its neighbors.

Griffith Labs' failure to warn those in the Willowbrook community that they were being exposed to a deadly carcinogen

- 89. As detailed above, Griffith Labs knew before it opened the Willowbrook facility that (a) toxicity data showed that EtO exposure was associated with human cancers and other harms; (b) the facility was located within the immediate proximity of homes, parks, schools, and small business; and (c) IEPA's (understated) modeling showed emissions were "several magnitudes higher than desirable."
- 90. Nevertheless, Griffith Labs made the conscious and purposeful decision not to warn those living and working in the Willowbrook community that they would be exposed to and caused to inhale a carcinogen on a routine and continuous basis.

91. As a result of Griffith Labs' failure in this regard, those who lived and worked in the Willowbrook community were not able to adequately protect themselves or avoid the emissions and were forced to unknowingly inhale a potent human carcinogen for years on end.

Griffith Labs failed to adhere to its own standard of care

- 92. Between 1984 and 1999, Griffith Labs made decisions at other EtO sterilization facilities in both the Unites States and other countries to use emissions control equipment far more effective at protecting the facilities' neighbors than the equipment it authorized for use at its Willowbrook facility.
- 93. As examples, in 1996 and 1997, Griffith Labs' EtO facilities in Willowbrook and Santa Teresa, NM, used roughly the same amount of EtO, but the emissions in Willowbrook were about 90-100x higher:

1996	Chambers	Aeration Rooms	Back Vents	EtO Used	Eto Emitted
Willowbrook	Controlled	Atmosphere	Atmosphere	423,721 lbs.	21,567 lbs.
Santa Teresa	Controlled	Controlled	Controlled	401,875 lbs.	239 lbs.
1997	Chambers	Aeration Rooms	Back Vents	EtO Used	Eto Emitted
Willowbrook	Controlled	Atmosphere	Atmosphere	516,187 lbs.	25,985 lbs.
Santa Teresa	Controlled	Controlled	Controlled	442,726 lbs.	260 lbs.

94. In 1998, Griffith Labs' EtO facility in Willowbrook used a little more than twice as much EtO as its facilities in Charlotte, NC, Glen Falls, NY, and Ontario, CA, but emitted 50 to 80 times more EtO into the atmosphere.

1998	Chambers	Aeration Rooms	Back Vents	EtO Used	Eto Emitted
Willowbrook	Controlled	Atmosphere	Atmosphere	595,203 lbs.	30,829 Ibs.
Charlotte	Controlled	Controlled	Controlled	234,572 lbs.	562 lbs.
Glen Falls	Controlled	Controlled	Controlled	262,318 lbs.	380 Ibs.
Charlotte	Controlled	Controlled	Controlled	277,249 lbs.	401 lbs.

95. These actions by Griffith Labs prove that, between 1984 and 1999, Griffith Labs was not only aware of technology that would dramatically reduce the EtO to which the neighbors

of its sterilization facilities would be exposed, but was already using that technology at its own facilities. There was no legitimate justification for its failure to use the same technology at Willowbrook.

Griffith Labs failed to properly consider science and medicine in making operational decisions

- 96. Throughout the entirety of the 1980s and 1990s, Griffith Labs continued to learn that respected public health agencies and organizations had concluded that EtO was extremely dangerous to human health. For example:
 - a. Between 1981 and 1994, the National Institute for Occupational Safety and Health ("NIOSH"); the US Department of Health and Human Services ("HHS"); US EPA; State of California; and World Health Organization ("WHO") concluded that EtO was, respectively, a potential occupational human carcinogen, with no safe level; "reasonably anticipated to be a human carcinogen"; "probably carcinogenic to humans"; "a carcinogen"; and "carcinogenic to humans".
 - b. In 1986, Griffith Labs learned that the state of California had modelled EtO emissions from Griffith Labs' facility in Southern California, and concluded that those emissions would cause a significant increase in EtO-related cancers for residents in the LA Basin.
- 97. Despite this information about the human health dangers associated with EtO, Griffith Labs took no significant precautions to protect its Willowbrook neighbors. To the contrary, throughout the 1980s and 1990s, Griffith Labs worked—independently and through EtO industry organizations, lobbyists, lawyers, and public relations agents—to improperly dispute and distort independent studies showing the dangers of EtO, and to cause EtO to appear to be less dangerous than it really was. These efforts resulted in the allowance of greater emissions from the Willowbrook facility, further endangering the area's residents, workers, and schoolchildren. Among other tactics, Griffith Labs and the EtO industry:

- a. successfully opposed implementation of back vent emission controls that would reduce EtO emissions;
- b. opposed limits on the EtO concentrations to which workers in sterilization facilities could be exposed; such workplace concentrations impact the health of the workers, of course, but also serve as the source of "fugitive" EtO emissions, which escape the facility, and expose the facility's neighbors; and
- c. funded scientifically baseless "studies," aimed at influencing independent public health studies on the health dangers of EtO with the ultimate purpose being to make EtO appear less dangerous to human health than Griffith Labs knew it to be.

Griffith Labs misled IEPA

- 98. Between 1984 and May 14, 1999, Griffith Labs misrepresented to IEPA, or omitted from disclosing to IEPA, the following significant information:
 - a. what Griffith Labs knew to be the dangers to human health caused by EtO emissions from sterilization facilities;
 - b. that Griffith Labs had emitted more EtO in 1983 than it told IEPA;
 - c. that Griffith Labs intended on emitting more EtO from the Willowbrook facility than IEPA modeled for;
 - d. that Griffith Labs' stack height where EtO would be released into the community was lower that what it told EPA;
 - e. that emissions control equipment to reduce EtO emissions were available to Griffith Labs when the Willowbrook facility was opened and for years thereafter before such equipment was installed;
 - f. that Griffith Labs was using emissions control equipment at its other EtO facilities that was far more protective of neighboring communities than the equipment its board of directors authorized for use at Willowbrook;
 - g. that the reporting of emissions from the Willowbrook facility was based on false assumptions about the effectiveness of Griffith Labs' emissions control equipment;

- h. that fugitive EtO emissions from the Willowbrook facility were far greater than reported;
- i. that Griffith Labs was working with the EtO industry to improperly influence science and make EtO appear less dangerous to human health than it actually is, with the purpose of influencing regulators to permit unsafe levels of EtO emissions.
- 99. By misleading IEPA on these issues, Griffith Labs was able to evade further regulatory scrutiny of the Willowbrook facility and its operations such that far more EtO was emitted into the Willowbrook community.

Griffith Labs failed to properly train the operators of the Willowbrook Facility

- 100. Between 1984 and May 14, 1999, Griffith Labs mandated that all EtO operations at the Willowbrook facility be conducted in strict compliance with its procedures and activity engaged with Willowbrook facility employees to ensure that those procedures were being followed.
- 101. As a result, up until the point where it sold the company on May 14, 1999, it was incumbent upon Griffith Labs to train on-site employees at the Willowbrook facility how to properly operate the facility so as to minimize EtO emissions to the Willowbrook community.
- 102. Griffith Labs failed to train those employees on how to operate the Willowbrook facility in a manner that would protect Willowbrook area residents, workers, and schoolchildren from the extraordinary health dangers posed by exposure to EtO emissions. Among other things, Griffith :abs:
 - a. failed to train employees to run aeration room emissions through the emission control system;
 - b. failed to train employees to run back-vent emissions through the emission control system;

- c. failed to train employees to keep chamber doors, aeration doors, and exterior doors closed and sealed so as to prevent EtO from escaping directly into the atmosphere; and
- d. failed to train employees to prevent and/or minimize off-gassing of sterilized products in areas that were not ventilated to emission controls.

Griffith Labs failed to responsibly audit the Willowbrook Facility

- 103. Between 1984 and May 14, 1999, Griffith Labs was responsible for conducting safety audits of the Willowbrook facility, and did in fact conduct such audits.
- 104. Griffith Labs, however, failed to conduct those safety audits in a manner that ensured that Willowbrook area residents, workers, and schoolchildren would be protected from the extraordinary health dangers posed by exposure to EtO emissions.
 - E. Micro-Biotrol Company's involvement at the Willowbrook facility does not negate Griffith Labs' liability.
- 105. On October 4, 1984, Griffith Labs formed a nominal corporate subsidiary, Micro Biotrol Company ("MBC"). On that date, Griffith Labs also purported to transfer certain, but not all, assets to MBC.
- 106. However, these events of October 4, 1984 do not negate Griffith Labs' liability for its own conduct as set forth above. Instead, Griffith Labs may be held liable as a joint tortfeasor under Illinois law.
- 107. The formation of MBC did not lead or cause Griffith Labs to reduce its involvement in the operations of the Willowbrook facility, or in the decision-making that caused and authorized the EtO emissions that in turn caused and contributed to Plaintiffs' cancers and other

illnesses. Indeed, the great majority of the Griffith Labs' conduct described in Paragraphs 33 – 104, occurred after October 4, 1984.

- 108. Further, Griffith Labs' purported asset transfer agreement with MBC did <u>not</u> transfer either (i) Griffith Labs' status or obligations relative to any permit issued by IEPA; or (ii) any liability for injury to Willowbrook area residents caused by emissions from the Willowbrook facility.
- 109. While MBC and its successors nominally operated the Willowbrook facility (hereinafter "Operators"), Griffith Labs' participation in facility operations exceeded the accepted norms of parental oversight, and Griffith Labs mandated and directed an overall course of action for the facility's operators which surpassed the control exercised as a normal incident of ownership. Facts relevant to this conclusion include, *inter alia*:
 - a. Griffith Labs' independent obligations and tortious conduct set forth above.
 - b. At all times through May 14, 1999, Griffith Labs was the 100% owner of the facility's operators.
 - c. While the facility's operators were nominally corporations themselves, upon information and belief, the boards of directors of these operators never met to consider matters related to the Willowbrook facility. Instead, all such board-level decisions were made by the Griffith Labs' board of directors.
 - d. There was no separate identity between Griffith Labs and the facility's operators. There was no arms-length relationship between them, including the fact that there was no documentation of the contracts and agreements between them, and no separate bank accounts. Griffith Labs and the facility's operators commingled funds in bank accounts that Griffith Labs controlled.
 - e. Griffith Labs required the facility's operators to conduct Willowbrook sterilization operations in strict compliance with Griffith Labs' procedures,

which, as stated above, were grossly deficient in protecting Willowbrook area residents from exposure to health endangering EtO concentrations, violated emissions standards established by the State of Illinois and Village of Willowbrook, and indeed caused and contributed to cause Plaintiffs' cancers and other illnesses.

- f. Griffith Labs provided the facility's operators its intellectual property, trade-secrets, and sterilization know-how to operate the Willowbrook facility.
- g. Griffith Labs directly participated in operational decisions that impact environmental health and safety.
- h. Griffith Labs controlled all operating funds; the facility's operators had no funds of their own, and could not have existed independently of Griffith Labs. The facility's operators had no access to funds without first requesting them, or borrowing them, from Griffith Labs.
- i. Griffith Labs paid for, or had to approve payment of, any expenditure related to the Willowbrook facility.
- j. Griffith Labs provided the facility's operators with financial and administrative services for essentially every aspect of Willowbrook operations, including information systems, finance and accounting, treasury, legal, insurance and risk management, taxation, human resources and employee benefits, strategic planning, management services, and systems and procedures.
- determined sterilization facilities were not in compliance with statute or regulation. For example, in 1993, Griffith Labs' Chairman, Dean Griffith, *personally* corresponded with the FDA regarding Griffith Labs' New Mexico EtO sterilization facility's failure to meet FDA regulations. Mr. Griffith personally directed operator employees on how to respond to the regulatory issues and informed the FDA that he was personally involved, personally directing the operator's plan of action to remedy violations, and requiring that operator personnel report to him directly regarding progress.

V. Ethylene Oxide as a Known Carcinogen

- 111. At the center of this case is that from approximately July 1984 to February 2019, Defendants emitted EtO, a known carcinogen, into the Willowbrook community. Before the Willowbrook facility ever began operation, Griffith Labs knew that its EtO emissions would be harmful to the communities surrounding its facility whose residents and workers would breathe the ambient air.
- 112. The DNA-damaging properties of EtO have been studied since the 1940s. For more than 40 years, EtO has been consistently recognized as dangerous, toxic, and carcinogenic.
- 113. In a 1977 report, the National Institute for Occupational Safety and Health ("NIOSH") concluded that occupational exposure to EtO may increase the frequency of genetic mutations in human populations. The report recommended that EtO be considered as mutagenic and potentially carcinogenic to humans and therefore that alternative sterilization processes be used whenever available. Occupational exposure studies like this one and others were and are relied upon by medical, scientific, and industry experts to determine the risk of harm of inhalation exposure to non-workers, like Plaintiffs and their decedents. Similarly, studies involving animals were and are relied upon by medical, scientific, and industry experts to determine the risk of harm of inhalation exposure to humans, like Plaintiffs and their decedents. Griffith Labs was or should have been aware of such studies which gave them the knowledge long before opening the Willowbrook facility that its EtO emissions would foreseeably harm persons in the neighboring communities.
- 114. In 1981, NIOSH released a new bulletin focusing on new evidence of the carcinogenic, mutagenic, and reproductive hazards associated with EtO, reiterated that EtO was

a potential occupational carcinogen, and reported that no safe levels of EtO exposure had been demonstrated.

- 115. In 1985, the U.S. Department of Health and Human Services ("U.S. HHS") Fourth Annual Report on Carcinogens classified EtO as "reasonably anticipated to be a human carcinogen."
- 116. Also beginning in 1985, the U.S. Environmental Protection Agency ("U.S. EPA") categorized EtO as "probably carcinogenic to humans."
- 117. In 1987, the State of California (home to at least two Sterigenics EtO sterilization facilities) officially designated EtO a carcinogen.
- 118. In the early 1990s, NIOSH published a high quality, long-term research study on EtO's carcinogenic impacts on humans. It tracked the mortality of 18,254 U.S. workers who had been exposed to EtO between the 1940s and the 1980s at sterilizer facilities much like the Willowbrook facilities. (According to Sterigenics Senior Vice President of Global Environmental, Health, and Safety, Kathleen Hoffman, the studied facilities included more than one operated by Sterigenics.7)
- 119. The study found causal links between exposure to EtO and increased mortality from lymphatic, hematopoietic, and breast cancers. It has since been heavily cited and relied on by major regulatory organizations including the World Health Organization ("WHO") and the U.S. EPA.

⁷https://yosemite.epa.gov/Sab/Sabproduct.nsf/B839FA45582C200185257D9500496B0E/\$File/EPA-+Sterigenics+Speaking+Points+for+IRIS+SAB+Review-Nov+2014.pdf

- 120. In 1994, the WHO International Agency for Research on Cancer ("IARC") found that "Ethylene Oxide is carcinogenic to humans," designating EtO as a Group 1 human carcinogen (the agency's highest risk classification for cancer).
- 121. In 2000, the U.S. HHS Ninth Annual Report on Carcinogens classified EtO as "known to be a human carcinogen."
- 122. In 2002, a U.S. Department of Labor's Occupational Safety and Health Administration ("OSHA") fact sheet on EtO stated that "[b]oth human and animal studies show that EtO is a carcinogen" and requires employers to provide clear signs and labels notifying workers of EtO's "carcinogenic and reproductive hazards."
- 123. In 2016, the EPA's Integrated Risk Information System ("IRIS") reclassified EtO as "carcinogenic to humans," and increased its estimate of EtO's cancer potency by 30 times. The U.S. EPA concluded that EtO is carcinogenic to humans by the *inhalation route of exposure* with a stated confidence level of "HIGH."
- 124. Acute exposure to EtO can result in nausea, vomiting, neurological disorders, bronchitis, pulmonary edema, and emphysema.
- 125. Chronic exposure to EtO can irritate the eyes, skin, nose, throat, lungs, and can cause harm to the brain and nervous system leading to headaches, nausea, memory loss, and numbness.
- 126. Chronic inhalation exposure to EtO can also cause reproductive and developmental impairments. Evidence recognized by the U.S. EPA indicates that inhalation

⁸ https://www.osha.gov/OshDoc/data General Facts/ethylene-oxide-factsheet.pdf

⁹ https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf

exposure to EtO can cause an increased rate of miscarriages in females. Evidence also indicates that EtO inhalation exposure can cause decreased sperm concentration and testicular degeneration in males.

- 127. Additionally, inhalation exposure to EtO can cause mutations and chromosomal damage that can lead to birth defects and cancer. Even when exposure to EtO diminishes or ceases, the frequency of sister chromatid exchanges (mutations/chromosomal alterations) have been found to remain elevated.
- 128. Chronic inhalation exposure to EtO also causes cancer. Evidence recognized by the U.S. EPA indicates that inhalation exposure to EtO causes various cancers including but not limited to lymphatic cancers, leukemia, and breast cancer. There is also evidence that EtO causes tumors in the body and reproductive issues in both men and women, as well as birth defects.
- 129. At all relevant times during their respective operations and/or direct participation with the Willowbrook facilities, Defendants knew or should have known that EtO is toxic and dangerous to human health and well-being. In addition, Defendants knew or should have known that EtO is classified as a carcinogen and has been determined to cause the various illnesses and ailments described above.
- 130. At all relevant times during their respective tenures at Sterigenics, Defendants Bob Novak and Roger Clark knew or should have known that EtO is toxic and dangerous to human health and well-being. In addition, Mr. Novak and Mr. Clark knew or should have known that EtO is classified as a carcinogen and has been determined to cause the various illnesses and ailments described above.

- 131. As described above, as early as in July 1984, Griffith was told by the IEPA that "the toxicity data provides evidence of human cancers of the pancreas, bladder, brain, central nervous system and stomach associated with EtO exposure. Various animal studies have shown carcinogenic, mutagenic, leukogenic, and teratogenic effects." In the same letter, the IEPA opined that there were "several methods" to reduce EtO emissions and requested a meeting to "discuss steps that can be taken to minimize emissions in order to reduce the ambient impacts to an acceptable level." That same information was known or should have been known by all Operators of the Willowbrook Facilities and all Defendants.
- 132. Accordingly, based on Griffith Labs' industry expertise as the pioneer of EtO sterilization, and all Defendants' knowledge of medical and scientific studies and reports dating back to the 1940s relating to the effects of EtO inhalation exposure (all of which scientific, medical, and industry professionals relied and rely upon to determine the risk of harm to persons like Plaintiffs and their decedents from inhalation exposure to EtO), and direct communications and warnings from IEPA, it was reasonably foreseeable to Defendants that their EtO emissions would far exceed levels safe for those in neighboring communities. Therefore, it was at all times reasonably foreseeable to Defendants that their Willowbrook operations would pose an unreasonable risk of harm to Plaintiffs and their decedents.
- 133. Notwithstanding Defendants' respective knowledge concerning the dangers of the sterilization operations in Willowbrook and the adverse health impacts of chronic inhalation exposure to EtO, Defendants chose to operate the facilities in a densely populated residential area and emitted hundreds of thousands of pounds of EtO into the environment without so much as

warning those who lived and worked in the Willowbrook area that they were being exposed to and inhaling EtO on a routine and continuous basis.

VI. Defendants' Operations and Conduct in Willowbrook

- 134. At all relevant times, the Willowbrook sterilization facilities were operated in a densely populated metropolitan area with 19,271 people living within one mile. Dense residential areas are located within approximately 0.3 miles to the immediate west, 0.6 miles to the southeast, 0.9 miles to the southwest, 0.7 miles to the north, 0.8 miles to the northeast, and 1.0 miles to the east.
- 135. At all relevant times, the Willowbrook facilities were close to numerous schools, daycare facilities, parks, government buildings, and businesses, including, at some point during operations, the following:
 - a. Schools: Gower Middle School (0.42 miles); Conev's Cradle Infant Care, Inc. (0.70 miles); St. Mark Christian Montessori (0.70 miles); Hinsdale South High School (0.76 miles); Gower West Elementary School (0.79 miles); Kingswood Academy (0.87 miles); KinderCare (1.0 mile); Our Lady of Peace School (1.22 miles); Concord Elementary (1.62 miles); Ready Set Grow (1.76 miles); Burr Ridge Middle School (1.86 miles).
 - b. **Parks and Government Buildings:** Willowbrook Police Department and Mayor's Office (0.07 miles); Willowbrook Community Park (0.45 miles); Indian Prairie Library (0.97 miles); Harvester Park (1.0 mile); Whittaker Park (1.03 miles); Burr Ridge Police Department (1.19 miles).
 - c. Businesses: Dance Duo Studio (0.1 miles); Dell Rhea's Chicken Basket (0.16 miles); Denny's (0.18 miles); Target (0.19 miles); La Quinta Inn (0.29 miles); Red Roof PLUS+ (0.3 miles); Diamond Edge Training (0.3 miles); BIG Gymnastics (0.68 miles); Darien Sportsplex (1.0 mile).

- 136. In addition, Willowbrook Town Center, which has nearly 200,000 square feet of retail stores, restaurants, and other businesses, is located 1.1 miles from the Willowbrook facilities.
- 137. Figure 1, below, depicts the area surrounding the Willowbrook facilities, in addition to a third facility that Defendants used for aerating products, and a lab Defendants used to test its sterilization process.

Figure 1



138. Upon information and belief, the aeration facility Defendants used, which was located at 7409 Quincy Street in Willowbrook and referred to as "Willowbrook III," did not have any pollution controls and, therefore, all EtO emissions from the facility went directly into the atmosphere. Further, upon information and belief, Defendants did not include their emissions from Willowbrook III in their reporting to the government.

- 139. Upon information and belief, the lab Defendants used, which was located at 16 W. 151 Shore Court in Burr Ridge, was used to test sterilization runs and, accordingly, involved the use of EtO. Upon information and belief, the lab did not have any pollution controls and, therefore, all EtO emissions from the lab went directly into the atmosphere. Further, upon information and belief, Defendants did not include its emissions from the lab in their reporting to the government.
- 140. From 1984 through their permanent closure in 2019, the Willowbrook facilities released EtO into the air in the Willowbrook area. The facilities stored EtO and sprayed it into gas chambers to sterilize medical equipment and pharmaceuticals. The Willowbrook facility on Quincy Street (built in 1984) holds fifteen gas chambers. The facility on Midway Drive holds four chambers (some built during the facility's original construction in 1999, some later in 2012).
- 141. The facilities operated 24 hours per day, emitting toxic, cancerous gas on a steady and continuous basis. As a result, EtO has been a constant element in the air inhaled by those who lived and worked near the facilities.
- 142. The half-life of EtO in the atmosphere has been reported at up to 211 days.¹⁰ Neither rain nor absorption into aqueous aerosols is capable of removing EtO from the atmosphere.
- 143. Table 1 depicts the facilities' *self-reported* EtO emissions from point sources and *self-reported* amounts of EtO treated on site:

¹⁰ https://publications.iarc.fr/115

Table 1

	Pounds of EtO Pounds of EtO				
Year	Emissions	Treated On-site			
1984	Unreported	Unreported			
1985	Unreported	Unreported			
1986	Unreported	Unreported			
1987	Unreported	Unreported			
1988	169,996	Unreported			
1989	97,518	Unreported			
1990	Unreported	Unreported			
1991	Unreported	Unreported			
1992	Unreported	Unreported			
1993	Unreported	Unreported			
1994	18,407	420,069			
1995	18,423	420,441			
1996	22,000	400,000			
1997	27,000	480,000			
1998	31,000	560,000			
1999	2,700	598,000			
2000	7,627	565,086			
2001	8,113	521,257			
2002	6,686	535,109			
2003	6,909	550,984			
2004	5,313	540,797			
2005	2,910	572,547			
2006	4,280	573,961			
2007	3,965	532,245			
2008	3,858	517,941			
2009	3,690	493,418			
2010	6,595	512,570			
2011	7,160	557,437			
2012	7,091	553,083			
2013	6,121	470,159			
2014	5,241	404,681			
2015	4,899	381,213			
2016	4,205	388,288			

144. There is little emissions data publicly available from before 1995. However, the ATSDR report notes that the available data suggests that "substantially higher ambient releases

prior to 1995 were likely." Indeed, emissions from 1988 and 1989 – approximately 170,000 pounds and 100,000 pounds respectively—are far more than the highest amount recorded in the contiguous 1995 – 2016 data set (31,000 pounds in 1998) and over 20 times more than emissions levels in 2016 (4,205 pounds). It is therefore reasonable to infer that the pre-1995 emissions of EtO were, at best, similar to those from 1998 and, at worst, closer to the colossal emissions in 1988 and 1989.

- 145. In addition to the reported point source emissions (EtO emitted through stacks), the facilities released significant volumes of fugitive (nonpoint source) emissions into the air.
- 146. Effective technologies to reduce EtO emissions to levels low enough to make the emissions a "non-significant contributor" to cancer risk have been available, cost-effective, and widely known since the 1980s; and on information and belief, Defendants have known it.
- 147. Despite the availability of these technologies, on information and belief, there have been periods during which the Willowbrook facilities had no pollution controls in place, had inadequate controls in place, and/or had pollution controls in place that failed to work due to the acts and omissions of the defendants.
- 148. On information and belief, there have also been periods during which the Willowbrook facilities, despite having some pollution controls in place, vented EtO directly into the air. Upon information and belief, since at least 2006 and up until July 27, 2018, the facilities allowed uncontrolled emissions of EtO from backvent valves in the sterilization chambers.

VII. A Pattern of Reckless Conduct

- 149. Sotera predecessor Sterigenics International, Inc. ("Sterigenics International") has been the subject of regulatory and administrative enforcement action relative to its EtO emissions in Europe. Beginning in 1992, Sterigenics International (now Sotera) operated a sterilization facility in Zoetermeer, a city in the western Netherlands. The Zoetermeer facility was located in an area with residential housing and numerous small business. In 2009, it was determined that Sterigenics International had been knowingly releasing amounts of EtO that exceeded the local Maximum Permissible Risk concentration into the air for years, was penalized, yet continued with its excessive emissions until it ultimately relocated its facility in 2010. According to the Public Prosecutor, Sterigenics International knew the emissions were unauthorized, but failed to act or even warn local residents about them or the associated dangers.
- 150. Sterigenics has also been faulted for neglecting safety in the United States. For example, after a major explosion in August 2004 at a sterilizing plant in Ontario, California, injuring four employees and forcing the evacuation of the plant and neighboring facilities, the U.S. Chemical Safety and Hazard Investigation Board (hereinafter "CSB") found that Sterigenics had failed to ensure its maintenance employees understood the hazards associated with EtO-based processes, which led them to manually override safety devices, causing the explosion. And it faulted Sterigenics management for not implementing "company-wide engineering control recommendations that could have prevented this explosion" and failing to follow recommendations on EtO concentrations disseminated by NIOSH.
- 151. Current and former Sterigenics employees elsewhere have raised safety concerns. For example, on the company's Glassdoor page, one former employee noted on June 25, 2013 that

"[t]here is a minimum attention to quality & safety which will backfire eventually."¹¹ Another stated on October 9, 2015 that "you're working with Ethylene Oxide which is extremely dangerous and the company seems to cut corners around safety at times."¹² Similarly, an "EtO A Operator" in the Charlotte, North Carolina facility reported on February 24, 2015 that "The maintenance team cuts a lot of corners."¹³

- 152. Former employees at the Willowbrook facilities have raised the same concerns, reporting, among other things, that Sterigenics and its predecessors:
 - a. routinely permitted chamber doors, aeration doors, and exterior doors to be left open, thereby allowing EtO to escape directly into the environment;
 - b. manipulated the EtO detection systems in the facilities to allow for an increased tolerance of EtO;
 - c. told employees to ignore warning lights in the facilities indicating high levels of EtO, and fired employees who complained about the warning lights;
 - d. directed employees to dump or wash toxic chemicals, including EtO and ethylene glycol, into the sewer system;
 - e. told an employee to take a leaking drum of EtO outside the facilities;
 - f. used off-site warehouse facilities without any pollution control or ventilation systems to store sterilized products that were still off-gassing EtO while, at the same time, leaving the exterior doors of those facilities open, causing the off-gassing EtO to go directly into the environment.
- 153. Key operational managers at the Willowbrook facilities actively participated in dangerous and harmful activities, which resulted in extraordinary uncontrolled emissions of EtO into the environment.

¹¹ https://www.glassdoor.com/Reviews/Employee-Review-Sterigenics-RVW2768416.htm.

¹² https://www.glassdoor.com/Reviews/Employee-Review-Sterigenics-RVW8236300.htm.

¹³ https://www.glassdoor.com/Reviews/Employee-Review-Sterigenics-RVW5987616.htm.